22 February 2024
EMA/CHMP/58610/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Carvykti

ciltacabtagene autoleucel

On 22 February 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Carvykti. The marketing authorisation holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted an extension to the existing indication to include treatment of adult patients with relapsed and refractory multiple myeloma who have received at least one prior therapy.

For information, the full indications for Carvykti will be as follows:[2]:

> CARVYKTI is indicated for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least ~~three~~ **one** prior therap**y**~~ies~~, including an immunomodulatory agent~~,~~ **and** a proteasome inhibitor ~~and an anti-CD38 antibody and~~, have demonstrated disease progression on the last therapy**, and are refractory to lenalidomide**.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union